REMARKS/ARGUMENTS

1. Response to the Rejection under 35 USC §103(a)

Claims 11-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pearlman et al. (WO/9918800) in view of Harvey (U.S. 6,013,636). This rejection is respectfully traversed.

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in the amended independent Claim 11.

More specifically, as recited in the amended independent Claim 11, Applicant's claimed dermatological composition consists of an avermectin compound in a concentration from about 0.05% to about 0.1% (w/v) in a lotion comprising glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water.

Pearlman et al. teach methods and kits for removing, treating or preventing head lice infestations in patients in need of such treatment, which includes topically applying to the lice-infested area an effective amount of a pediculostatic agent for a time sufficient to immobilize the lice, followed by combing to remove the lice and nits.

This method optionally includes application of a pediculocide, together with the pediculostatic agent, which includes pyrethrins, permethrin, lindane, malation, carbaryl, ivermectin, and combinations thereof. Pearlman et al. specifically teach that the pediculocides active ingredients can be used at levels effective to achieve their intended results, which are at a concentration from about 0.25% to about 2.5% (see page 19, third paragraph).

More specifically, Pearlman et al. teach to use Cetaphil lotion as a pediculostatic agent, and optionally use ivermectin as a pediculocide at a concentration of from about 0.25% to about 2.5% to treat head lice for one or a few

times, with a limited skin contact time with the topic composition.

Applicant points out Pearlman et al. teach substantially higher ivermectin concentration than that in Applicant's claimed composition. The lowest concentration of ivermectin in Pearlman et al.'s composition is 2.5 times higher than the highest concentration of Applicant's claimed composition as defined in the amended Claim 11.

As discussed in the previous response, it is important to understand that Applicant's claimed composition is used for treating various forms of dermatological conditions, which requires daily application for a substantial period of time, i.e., from several weeks to several months. Applicant has discovered that the instant dermatological composition containing a very low concentration of ivermectin from 0.05% to 0.1% is effective in treating various dermatological conditions without causing skin irritation, or increase of skin sensitivity after daily use of the instant composition for a substantial period of time up to several months (see Examples 4-14, particularly Example 9).

Therefore, Applicant's topical composition containing a very low concentration of ivermectin in a lotion defined in Claim 11 has strong clinical advantages in treating the dermatological conditions described above.

In this context, Pearlman et al. fail to teach or recognize the clinical need and advantages of using a low concentration of ivermectin in combination with a Cetaphil lotion.

The deficiencies of Pearlman et al. are not overcome by Harvey.

Harvey teaches a composition comprising an anthelmintic macrocyclic lactone, a vegetable oil, and a co-solvent of alcohol having four or more carbon atoms, which is suitable for treating helminthiasis (i.e., infection with a parasitic worm) in animals. The macrocyclic lactone includes avermectin, ivermectin, doramectin, abamectin, milbemycin, and moxidectin.

More specifically, Harvey teaches three different compositions: (1) an injectable solution containing 0.5-5% of abmectin or ivermectin; (2) a pour-on solution containing 0.5-5% of abmectin or ivermectin; and (3) an oral administration containing 0.1-10% of abmectin or ivermectin, wherein all three compositions containing a

vegetable oil, and a co-solvent of alcohol having four or more carbon atoms (see Column 1, line 28 to Column 2, line 34, and Column 11, lines 54-62 of the reference).

It should be emphasized that for topical application, Harvey specifically teaches the pour-on solution containing 0.5-5% of ivermectin, nothing less than that.

Harvey further teaches that they have found by using sesame oil, soya bean oil or corn oil together with a co-solvent of alcohols, it is possible to make a stable solution containing avermectins, ivermectin, doramectin, abamectin, milbemycin or moxidectin, which allows the anthelmintic to remain in solution even when stored in cold conditions, whilst at the same time allowing the controlled release of the drug into the animal's body, for use against both internal and external parasites.

Therefore, Harvey's composition, functioning as an effective anthelmintic, is a combination of ivermectin with the vegetable oil and the co-solvent of alcohol, and the effectiveness of the composition depends on the vegetable oil and the co-solvent. However, a medium based primarily on vegetable oils is not suitable for topical use for substantial period of time required for the purpose of treating the dermatological conditions described in the present invention, because it is known the oil clogs pores and it can worsen these dermatological conditions.

Based on Harvey's teaching, one ordinary skilled in the art would not use less than 0.5% of ivemectin for a topical composition, because Harvey explicitly teaches that the low end concentration of ivemectin in the pour-on solution is substantially higher than the concentration in the oral administration.

On the other hand, as discussed above, Pearlman et al. teach ivemectin concentration from 0.25% to 2.5% in the topical composition, which is the level deemed effective.

Based on such combined teachings, one ordinary skilled in the art would not be motivated to try to use less than half of the lowest concentration taught by Pearlman et al. or less than one fifth of the lowest concentration taught by Harvey in a topical composition. Even if one combines, in the manner suggested by the Examiner, one would only be able to obtain a topical composition containing 0.5-5% of ivemectin taught by Harvey and the Cetaphil lotion taught by Pearlman et al.

Therefore, Applicant maintains that Applicant's claimed dermatological composition defined in the amended Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

12/22/2008
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